IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FMC CORPORATION, *Plaintiff,* vs. SUMMIT AGRO USA, LLC and SUMMIT AGRO NORTH AMERICA HOLDING CORPORATION, *Defendants.*	PUBLIC VERSION C.A. No. 14-51-LPS **JURY TRIAL DEMANDED** [redacted]

PLAINTIFF FMC CORPORATION'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR PRELIMINARY INJUNCTION

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I. INTRODUCTION

FMC Corporation ("FMC") respectfully moves for a preliminary injunction to (i) stop Defendants' infringement of FMC's U.S. Patent No. 7,169,952 (the "'952 Patent"), (ii) stop Defendants' unlawful and misleading labeling of their Blanket 4F product in clear violation of the Tariff Act, 19 U.S.C. §1304(a), and (iii) prevent further irreparable harm to FMC.

Defendants have imported, and are manufacturing and selling Blanket 4F and SFZ-4SC products containing, sulfentrazone made by a process that infringes the '952 Patent. In addition, Defendants' Blanket 4F product fails to designate China as the country of origin of the sulfentrazone, and thus, the product labeling deceives consumers and violates both the Tariff Act and the Lanham Act.

Preliminary injunctive relief is needed to ensure that FMC's patent rights are protected, the Tariff Act's labeling mandates are enforced, and irreparable harm to FMC is prevented.

II. STATEMENT OF FACTS

A. The U.S. Market and Distribution Channels for Herbicides Based on Sulfentrazone

Sulfentrazone is an herbicide invented by FMC that is effective in eradicating weeds found in agricultural and non-agricultural environments. Sulfentrazone is particularly effective in halting weed growth in soybean, sunflowers, vegetable, and tobacco crops. Declaration of John Kasper ¶ 3. FMC currently markets eight brands of sulfentrazone products in the U.S.: Authority®, Spartan®, Zeus®, BroadAxe®, Blindside®, Echelon®, Dismiss®, and Solitare® (collectively, the "FMC Products"). Declaration of John Cummings ¶ 9. These products include stand-alone sulfentrazone formulations and pre-mix formulations.

FMC's sulfentrazone products are sold through a three-tier distribution and sales network. Kasper ¶ 31. In the first tier, FMC sells to major distributors. *Id.* ¶ 32. In the second

tier, distributors sell to retailers. In the third tier, retailers sell directly to farmers, growing cooperatives, and agricultural companies. Retailers typically do not have exclusive arrangements with a single distributor. But they do develop strong alignments with a primary distributor for it to supply most of their product needs, while buying a small percentage of other goods from one or two other distributors. *Id.* ¶ 33. [redacted] FMC's sales in the United States of its sulfentrazone products in 2011, 2012 and 2013, and its expected sales in 2014, absent infringement, [redacted]. Declaration of Kenneth W. Arnold ¶ 3.

B. FMC's '952 Patent

FMC is the owner, by assignment, of the '952 Patent entitled "Process to Prepare Sulfonamides." **EX15; EX17.**[1] Sulfentrazone is made by a reaction called sulfonylation, which combines an aniline compound and a sulfonating agent, such as methanesulfonyl chloride. This process forms hydrochloric acid ("HCl") as a by-product. Declaration of Leland Smeltz ¶ 9.

A buildup of HCl during the sulfonylation reaction is undesirable because it can reduce

[1] All exhibits ("**EX**") referenced herein and in supporting declarations are attached to the Declaration of Daniel M. Silver.

the yield of sulfentrazone. To solve this problem, FMC scientists developed a process referred to as the "pyridine process," which neutralized the HCl. *Id.* ¶ 11.

Although the pyridine process successfully made sulfentrazone, it was expensive, potentially hazardous, and the pyridine had to be disposed of at the end of the reaction. *Id.* ¶ 13. Moreover, it resulted in another byproduct that reduced the amount of sulfentrazone formed. *Id.* ¶ 13. By the Fall of 1998, FMC scientists discovered that N,N-dimethylformamide ("DMF") in combination with relatively high temperatures produced sulfentrazone more efficiently and cost effectively, eliminated drawbacks and yielded greater quantities. Declaration of Thomas Sedergran ¶¶ 17-22. The '952 Patent resulted from this research.

C. Defendants' Entry Into the U.S. Market with Competing Products

FMC spent millions of dollars to develop its sulfentrazone business, and to support registration of the FMC Products with the EPA. Cummings ¶¶ 11-12. An herbicide cannot be sold in the United States without EPA and state registrations. In support, FMC commissioned over 1,000 scientific studies, over 600 of which were submitted to the EPA. *Id.* ¶ 10.

Defendant Summit Agro USA ("Summit USA") and Summit Agro North America Holding Corp. ("Summit Holding") both obtained "Me-Too" EPA registrations for sulfentrazone and a formulated sulfentrazone composition ("SAUSX-01"), by citing to and relying on FMC studies. *Id.* ¶¶ 13-14. The EPA approves Me-Too Products based on a finding that the pesticide is identical or substantially similar to a registered pesticide. Thus, the EPA found that SAUSX-01 and Defendants' sulfentrazone were identical or substantially similar to FMC's sulfentrazone product(s). *Id.* ¶ 14; **EX10**; **EX60**; **EX61**.

After receiving its registration, Summit Holding granted a private label to Summit USA, allowing it to sell SFZ-4SC, and to [redacted] Tenkoz, allowing it to sell Blanket 4F ("Blanket"). Cummings ¶ 17. Blanket and SFZ-4SC are formulated to nearly identical

formulation ratios as FMC's Spartan® brand product, using imported sulfentrazone from China.[2] *Id.* ¶ 15.

D. Defendants' Infringing Process

FMC wrote to Summit USA in July of 2013 noting its understanding that Summit USA intended to import sulfentrazone into the United States and informing Summit of the '952 Patent. Declaration of Peter A. Sullivan ¶ 2. When, in response, Summit USA alleged that the '952 Patent was invalid over U.S. Patent No. 5,990,315 to Dumas (the "'315 Patent"), FMC became suspicious. *Id.* ¶ 3.

On December 17, 2013, after exchanging several communications, [redacted] Prior to that meeting, FMC had a sample of Defendants' product tested. The test results identified the presence of a DMF adduct, which could only have been created from a DMF-based sulfonylation reaction. [redacted] it indicated that the process used to make Defendants' product used DMF as in the '952 Patent. Declaration of Dr. Jeffrey Winkler ¶¶ 30-31. [redacted] the testing, FMC concluded that Defendants infringe at least claims 25-28 of the '952 Patent.

E. The Effect of the Infringing Products

Defendants are importing sulfentrazone that infringes the '952 Patent, and are manufacturing and selling infringing products formulated from that sulfentrazone to a nearly identical formulation ratio as FMC's Spartan® product. Cummings ¶ 15. Defendants are also competing with FMC's pre-mix sulfentrazone products by employing a "tank-mixing" strategy. A "tank-mix" is when growers create a combination product on their own by mixing two pesticides in a single tank or canister. Kasper ¶¶ 43-44. Defendants' instructions to farmers to

2. **EX15, EX18, EX19, EX20, EX54**: Bills of Lading for Nutrichem Shipments.

make their own tank mixes risks creation of sub-lethal doses of pesticide and, potentially, a sulfentrazone-tolerant weed population. *Id.* ¶ 45.

[redacted] *Id.* ¶ 46. The potential loss of sales to Tenkoz is uncertain because Defendants have just recently entered the market. But, FMC has in fact lost sales and expects more significant losses going forward. *Id.* ¶ 36. Blanket 4F is offered for sale to farmers at prices that undercut FMC's prices by 40 to 50%. *Id.* ¶ 41.

Since the launch of Blanket 4F, [redacted]

F. FMC's Labeling of Spartan

FMC conspicuously marks its Spartan® products with the country of origin of the active ingredient as follows: **"ACTIVE INGREDIENT MADE IN CHINA AND FORMULATED AND PACKAGED IN USA."** *Id.* ¶ 56; **EX45.**

G. Defendants' Labeling of Blanket

The product label for Blanket indicates that Blanket is manufactured at EPA Est. No. 70815-GA-002. Although this EPA Est. No. corresponds to EJB Industries, Inc., Summit Holding remains the manufacturer of the product, inasmuch as Summit Holding is the registrant and is ultimately responsible for manufacture. Indeed, shipping documentation accompanying a pallet of Blanket product states: "Summit Agro Material Number N6AZZBLKTFINPKG." Cummings ¶21; **EX65; EX66.**

The Blanket product neither designates China as the country of origin of the product, nor designates China as the country of origin of the active ingredient. The product label states:

Distributed by:
Tenkoz, Inc
1725 Windward Concourse, Suite 1410
Alpharetta, GA 30005

EX12. Thus, not only does the Blanket label fail to identify by name any manufacturer of the product, it also fails to identify that the sulfentrazone is manufactured in China.

III. ARGUMENT

A. Legal Standards for Preliminary Injunction

"A plaintiff seeking a preliminary injunction must establish [1] that it is likely to succeed on the merits, [2] that it is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in its favor, and [4] that an injunction is in the public interest." *AstraZeneca LP v. Apotex Corp.*, 633 F.3d 1042, 1049 (Fed. Cir. 2010). No one factor is dispositive. *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1365 (Fed. Cir. 2002).

B. A Preliminary Injunction Should Issue Against Defendants on FMC's Patent Infringement Claim

1. FMC Will Likely Succeed in Proving Infringement

FMC must show that it will likely prove infringement of one claim of the '952 Patent and that at least that one claim will likely withstand a validity challenge. *AstraZeneca*, 633 F.3d at 1050. FMC need only show that it is "more likely than not" that Defendants infringe. *Revision Military, Inc. v. Balboa Mfg. Co.*, 700 F.3d 524, 526 (Fed. Cir. 2012).

a. FMC Will Likely Prove Infringement of Claims 25 to 28

Claims 25 to 28 of the '952 Patent each depend from claim 18, and recite a process for making sulfentrazone by reacting an aniline with a sulfonating agent in the presence of dimethylformamide ("DMF") at a temperature range of about 120°C to about 160°C for about 3 to about 7 hours. Claim 25 recites that the sulfonating agent is methanesulfonyl chloride. Claims

26 to 28 further recite a solvent, the solvent is aromatic, and the solvent is toluene.

To establish infringement, the claim terms in dispute must first be construed, and then the claims compared to the accused process. *Markman v. Westview Instr., Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The terms used in claims 25 to 28 are common terms in chemistry. Therefore, one of ordinary skill in the art would interpret these terms in accordance with their plain and ordinary meaning in the chemical arts. Winkler ¶ 20.

Defendants are expected to contend that temperatures [redacted] are not encompassed by "about 120 °C. The use of the term "about" in conjunction with 120 °C demonstrates that the inventors did not intend to limit the temperature to 120 °C. When used in connection with the end of a range, the term "about" provides for variance. *See Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1293 (Fed. Cir. 2010) (en banc) (noting that the term "about" extends the scope of literal infringement beyond the specific range (citing *U.S. Philips Corp. v. Iwasaki Elec. Co. Ltd.*, 505 F.3d 1371, 1379 (Fed. Cir. 2007)); *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1554 (Fed. Cir. 1996) (term "about" must be given "reasonable scope . . . . in light of the technology embodied in the invention").

A variance in the recited temperature range is evident from the '952 Patent specification, which provides examples for making sulfentrazone at temperatures ranging from 110 °C to 148 °C. **EX15** at col. 5, line 50; col. 7, line 35; Winkler ¶ 22. Indeed, Example 1 of the '952 Patent is run at a reaction temperature of 110 °C using N-methylpyrrolidone, which has the same role as DMF in the reaction. *Id.*

The '952 Patent also teaches that "a particularly preferred solvent that can be used in the present invention is toluene." *Id.* The boiling point of toluene is 110.6 °C. *Id.* While one of the examples teaches the use of toluene at 140-145 °C using an elevated pressure to raise toluene's

boiling point, most of the toluene reactions in the examples are performed at much lower temperatures (Example 1, 110 °C; Example 5, 119-120 °C; Example 9, about 115 °C). *Id.* Thus, the patent specification teaches that acceptable reaction temperatures include temperatures somewhat lower than 120 °C, [redacted] *Id.* ¶ 23.

b. Defendants Literally Infringe Claims 25 to 28

[redacted]

	Defendants' Process	Claim 25 of '952 Patent
Reagent 1	[redacted]	The aniline
Reagent 2	[redacted]	"MethylSO_2Z" includes methanesulfonyl chloride
Catalyst	[redacted]	DMF
Temperature	[redacted]	"About 120 °C to about 160 °C"
Product	[redacted]	Sulfentrazone

c. Defendants Also Infringe Claims 25 to 28 under the Doctrine of Equivalents

The doctrine of equivalents applies to claims involving ranges. *See, e.g., Warner-Jenkinson v. Hilton Davis Chemical Co.*, 520 U.S. 17, 32-33 (1997) (allowing consideration of the equivalents for claim to a pH range "from approximately 6.0 to 9.0"); *U.S. Philips Corp. v. Iwasaki Elec. Co. Ltd.*, 505 F.3d 1371, 1379 (Fed. Cir. 2007) (rejecting argument that allowing

equivalents would "vitiate the recited end points of the stated range"); *Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097, 1107 (Fed. Cir. 2002) (permitting the use of the doctrine of equivalents for values above claimed range where it did not eliminate altogether the upper limit).

The difference between 120 °C and a somewhat lower temperature in the disclosed catalytic process known to make sulfentrazone is insubstantial and equivalent. Both "about 120 °C" and somewhat lower temperatures have the same function when coupled with DMF, or another catalyst performing the same role, and they cause the reaction to proceed in the same way, *i.e.*, by application of heat. Thus, performing the reaction at about 120 °C [redacted] achieves the same result. Winkler ¶ 25.

The Federal Circuit has upheld infringement under the doctrine of equivalents for this amount of variation from a stated end point in a range. *See, e.g., U.S. Philips*, 505 F.3d at 1379 (range of mercury concentration in a lamp of 1.2 to 2.0 x 10^{-4} units could infringe by equivalents a claim having an upper endpoint of 1.0 x 10^{-4} units).

The '952 Patent is entitled to a full range of equivalents. The claims were not amended during prosecution, and no prosecution history estoppel applies. The patent examiner stated that the new process was patentably distinct because "[t]he cited prior art neither teaches nor suggests the instant catalytic, high temperature reaction." **EX35**, p. 20. Accordingly, Defendants infringe claims 25 to 28; if not literally, under the doctrine of equivalents.

d. Defendant's Sole Challenge to the '952 Patent Lacks Merit

[redacted] that the '952 Patent is invalid over the '315 patent -- a patent already considered by the Patent Office during prosecution of the '952 Patent. **EX16.** An alleged infringer must overcome the presumption of validity with clear and convincing evidence. This burden is particularly high where, as here, the

prior art reference was already considered during prosecution. *See, e.g., Impax Labs., Inc. v. Aventis Pharm., Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008) (citations omitted).

e. The '315 Patent Does Not Anticipate Claims 25 to 28

The '952 Patent was filed on June 1, 2001, and claims priority to a provisional application filed on June 5, 2000. **EX52**. The inventors' written records show that DMF as a catalyst to make sulfentrazone was invented as early as [redacted] Winkler ¶ 37.

The '315 Patent, alleged to invalidate the '952 Patent, was filed on April 30, 1999, and claims priority to a provisional application filed on May 29, 1998. It became publicly available when it issued on November 23, 1999, less than a year before the filing date of the '952 Patent.

Under 35 U.S.C. §119(e), the written description of a provisional application must adequately support and enable subject matter claimed in the non-provisional application to which it claims priority. *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002). Dumas' provisional application neither disclosed DMF nor enabled the use of DMF to make sulfentrazone. Thus, its May 29, 1998 filing date has no priority for teaching DMF.

DMF first appeared in Dumas on April 30, 1999, when its non-provisional application was filed. Neither the addition of DMF to the application, nor its publication upon issuance of the '315 patent, pre-dates FMC's invention. *See* Winkler ¶ 34.

Under 35 U.S.C. §102 as it was then in effect, patentability is defeated if a prior publication or an earlier filed patent application describes the claimed subject matter. *See* 35 U.S.C. §§ 102(a), 102(b), 102(e). The difference between prior publications under 102(a) and 102(b) is timing. A public disclosure occurring more than one year before the earliest effective filing date of a patent application is prior art under 102(b), and bars patentability.

35 U.S.C. § 102(b) does not apply because the '315 Patent was not available to the public more than one year before the filing date of the '952 Patent. The '315 Patent may qualify as

prior art under 102(a) and/or 102(e) based on its publication date of November 23, 1999 and/or its earliest effective filing date with regard to the DMF disclosure, April 30, 1999. But this is defeated because the invention claimed in the '952 Patent predates the filing date DMF was included in the non-provisional application issued as the '315 Patent.

The Dumas provisional cannot anticipate claims 25 to 28 of the '952 Patent because it does not disclose DMF, and the DMF disclosure in the '315 patent is not prior art. *In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1371 (Fed. Cir. 2007) ("Anticipation requires disclosure of each and every claim limitation in a single prior art reference....").

f. Claims 25 to 28 Are Not Obvious In View of Dumas

The Dumas provisional does not render obvious claims 25 to 28 of the '952 Patent because it does not teach or suggest using DMF or any catalyst structurally similar to DMF. Winkler ¶¶39-41. Rather, it teaches using a "source of soluble halide." **EX29**, page 3, line 16. But DMF is not a source of a halide, nor is there any halide in DMF. Winkler ¶ 39.

Dumas also discloses "quaternary ammonium salts, quaternary phosphonium salts, salts of tertiary amines, salts of basic nitrogen-containing heterocycles, [and] salts of [the aniline]." **EX 29**, page 3, lines 32-34. DMF is none of these. Winkler ¶ 40.

2. FMC Will Be Irreparably Harmed Absent a Preliminary Injunction

The illegitimate introduction of a new entrant to the sulfentrazone market will lead to irreversible damage to the relationships between FMC and its distributors. *See Robert Bosch, LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1152 (Fed. Cir. 2011) (reversing denial of injunction based in part on impact to market share and access to customers). Already one of FMC's distributors – Tenkoz – has been targeted by Defendants, and is substituting some of its supply with Accused Products. Kasper ¶¶ 36, 50. [redacted]

[redacted]

The introduction of infringing sulfentrazone will also likely harm the reputation of FMC. *See Douglas Dynamics v. Buyers Prods. Co.*, 717 F.3d 1336, 1344 (Fed. Cir. 2013) ("Irreparable injury encompasses different types of losses that are often difficult to quantify, including lost sales and erosion in reputation and brand distinction."). Through FMC's efforts, sulfentrazone enjoys a solid reputation for efficacy and has demonstrated no incidence of resistance building. Kasper ¶ 45. But, Defendants are selling Blanket, through Tenkoz, to farmers with instructions to make formulations that will replicate the formulation percentages for FMC's Authority® brand premix products. *Id.* ¶¶ 43-44. This relatively uncontrolled tank-mixing program can lead to lack of efficacy and, worse, resistance to sulfentrazone itself because it increases the risk that farmers' will create sub-lethal doses of pesticide, thereby creating a tolerant weed population. *Id.* ¶ 45. To the extent that this strategy includes combining Accused Products with an FMC sulfentrazone product, the reputation of FMC and its products also will be jeopardized.

A new entrant will also negatively impact FMC's access to retailers and growers. If a distributor switches to Blanket, FMC potentially loses some or all of the retailers buying from that distributor (and by extension, the customers of that retailer) due to the strong alignments between distributor and retailer. *Id.* ¶¶ 33-35. With respect to vertically integrated distributors, FMC almost certainly would lose access to the captive retailers controlled by those distributors. *Id.* Even if a distributor sells both FMC's and Defendants' sulfentrazone, retailers will most certainly curtail their purchases of FMC sulfentrazone in the face of a lower cost alternative. *Id.*

The infringement also is itself harmful to FMC's reputation. The court in *Douglas Dynamics* noted the reputational loss in not enforcing patent rights:

> Douglas's reputation as an innovator will certainly be damaged if customers found the same "innovations" appearing in competitors' snowplows, particularly products considered less prestigious and innovative. Douglas's reputation would be damaged if its dealers and distributors believed it did not enforce its intellectual property rights. Lastly, the evidence shows that Douglas had never licensed the infringed patents, and intentionally chose not to, so that it could maintain market exclusivity. Exclusivity is closely related to the fundamental nature of patents as property rights.

717 F.3d at 1344-45.

To combat further loss of customers, FMC has had to implement steps on an accelerated basis to compete with this lower cost illegitimate market entrant. Kasper ¶ 39. These steps will lead to lower prices and lower profitability, which FMC will not be able to recover. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382-83 (Fed. Cir. 2006) (finding irreparable harm).

Further, Defendants' infringement will inevitably lead to irreversible price erosion. *See Celsis in Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) ("Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm."). FMC has enjoyed a substantial premium for its products because of the cost efficiency afforded by its '952 Patent position. But Blanket is now offered at a 40 to 50% discount. *Id.* ¶ 41. The nature of the harm is even more acute where, as here, the parties are direct competitors. "Where two companies are in competition against one another, the patentee suffers the harm—often irreparable—of being forced to compete against products that incorporate and infringe its own patented inventions." *Douglas Dynamics*, 717 F.3d at 1345.

3. The Balance of Equities Clearly Favors Entry of an Injunction

FMC will suffer irreparable harm if Defendants are allowed to continue to import and sell infringing sulfentrazone. By contrast, Defendants will suffer no such harm. Moreover, a preliminary injunction would not preclude Defendants from selling sulfentrazone made with a non-infringing process. Defendants could sell sulfentrazone produced under FMC's prior

pyridine process, now in the public domain, and under their own EPA registrations, but are not entitled to continue to infringe the '952 Patent. *See, e.g., Robert Bosch*, 659 F.3d at 1156 (quoting *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986) ("One who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected."); *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005) ("[A]n alleged infringer's loss of market share and customer relationships…does not rise to the level necessary to overcome the loss of exclusivity experienced by a patent owner due to infringing conduct.").

4. The Public Interest Favors Encouragement of Innovation and Protection of Intellectual Property Rights

No critical public interest precludes a preliminary injunction. FMC will continue to meet market demands. Arnold ¶ 5. And the pyridine process remains as a non-infringing means of manufacturing sulfentrazone. The public loses nothing if Defendants are enjoined.

C. A Preliminary Injunction Should Issue Against Defendants on FMC's False Designation of Origin Claim

1. FMC Is Likely to Succeed on the Merits of its False Designation of Origin Claim

a. The Blanket Label Clearly Violates the Tariff Act

The Tariff Act requires that "every article of foreign origin (or its container …) imported into the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article (or container) will permit in such manner as to indicate to an ultimate purchaser in the United States the English name of the country of origin of the article." 19 U.S.C. §1304(a). With respect to the imported components of goods finally manufactured in the United States, the Tariff Act's mandate applies unless the work or material added effects a "substantial transformation." 19 C.F.R. § 134.1(d)(1); 19 C.F.R. § 134.35(a). To

qualify as a "substantial transformation," a domestic formulation must effect a change that results in a different "name, character, or use" from that of the imported article. 19 C.F.R. § 134.35(a); *see also, e.g.*, *Uniroyal, Inc. v. United States*, 542 F.Supp. 1026, 1029-30 (Ct. Int'l Trade 1982) ("minor assembly operation" is not a substantial transformation; relaxing the standard would "open the door wide to frustration of the entire purpose of the marking statute").

Customs Rulings have consistently applied the "substantial transformation" rule to the imported active ingredients in pesticides. *See* **EX67,** New York Ruling Letter NY N056869 (Apr. 24, 2009) (no substantial transformation in the mere addition of stabilizers and processing aids); **EX68,** Headquarters Ruling Letter HQ 561330 (July 2, 1999) (substantial transformation requires mixture of chemical compounds "to form a different substance and the individual properties of each ingredient are no longer discernible"); **EX69,** Headquarters Ruling Letter HQ 559932 (Oct. 8, 1996); **EX70,** Headquarters Ruling Letter HQ 734558 (July 22, 1992).[3]

The final formulation of Blanket in the United States does not result in a substantial transformation of the sulfentrazone. Cummings ¶ 22. Were it otherwise the EPA would require a new product registration. *Id.* Thus, by failing to mark China as the country of origin of the active ingredient on the Blanket label, Defendants have clearly violated the Tariff Act.

b. The Blanket Label Violates the Lanham Act

Because the Blanket label violates the Tariff Act it violates the Lanham Act as well. Section 43(a) of the Lanham Act, 25 U.S.C. §1125(a)(1)(B), provides in relevant part as follows:

> (1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce ... ***any false designation of origin***...which...(B) ...misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods...shall be liable in a civil action by any person who believes that he or she is likely to be damaged by such act. (emphasis supplied).

[3] Rulings of the Bureau of Customs and Border Protection, formerly called the US Customs Service, are available online at http://rulings.cbp.gov/.

Two lines of authority address whether a violation of the Tariff Act is, without more, a violation of Section 43(a) of the Lanham Act. The first line of cases (the "*Alto* line of cases") holds that a violation of the Tariff Act is likely to result in consumer confusion and, thus, violates the Lanham Act as a matter of law. *See Alto Prods. Corp. v. Ratek Indus. Ltd.*, No. 95-cv-3314, 1996 WL 497027, at *5 (S.D.N.Y. Sept. 3, 1996); *Bohsei Enters. Co., U.S.A. v. Porteous Fasteners Co.*, 441 F. Supp. 162, 164-65 (C. D. Cal. 1977). The second line of cases requires independent proof of consumer confusion, reasoning that consumer confusion is a question of fact and cannot be presumed as a matter of law. *York Group, Inc. v. York S., Inc.*, No. H-06-0262, 2006 WL 3057782, at *5-7 (S.D. Tex Oct. 25, 2006). The Third Circuit has not addressed whether a violation of the Tariff Act constitutes a *per se* violation of the Lanham Act. Regardless, FMC is still likely to succeed because it has submitted fact and expert evidence establishing that the ultimate purchasers of Spartan and Blanket prefer products of domestic origin.

c. A Violation of the Tariff Act is a *Per Se* Violation of the Lanham Act

In passing the Tariff Act in 1890 and again in 1930, Congress presumed that consumers would make buying decisions based in part on country of origin and, in particular, that they would prefer American goods. *See, e.g., United States v. Ury*, 106 F.2d 28, 29 (2d Cir. 1939) ("The purpose [of the Tariff Act] was to … confer an advantage on domestic producers of competing goods. Congress was aware that many consumers prefer merchandise produced in this country."); *United States. v. Friedlaender & Co*, 27 C.C.P.A. 297, 302 (1940); *see also Globemaster, Inc. v. United States*, 340 F. Supp. 974, 975-76 (Cust. Ct. 1972).

"Logic dictates that … a consumer encountering goods with no marking as to country of origin will assume that they are American-made, thus creating a likelihood of confusion with

goods which are, in fact, American-made." *Alto,* 1996 WL 497027 at *5. "To hold that omission of such a material fact [as country of origin] is not such a false representation as to affect competition of the sale to the detriment of a seller who complies with the mandate of 19 U.S.C. § 1304 requires an utterly naive view of the realities of the market place." *Id.,* citing *Bohsei,* 441 F. Supp. at 164. Thus, proof of a violation of the Tariff Act's mandate is itself proof of deception or confusion. *Alto,* 1996 WL 497027 at *8 (granting plaintiff's motion for summary judgment and enjoining defendant from further acts of false designation of origin). To hold otherwise would reward a defendant who willingly chooses to ignore the Tariff Act, and "promote disregard for the provisions of 19 U.S.C. § 1304." *Bohsei*, 441 F. Supp. at 164.

d. The Blanket Label Creates a Likelihood of Consumer Confusion

Omission of the country of origin on the Blanket label necessarily implies that the product, including the active ingredient, is of American origin. *See Bohsei,* 441 F. Supp. at 164 ("The law of false representation must necessarily include the omission of the material fact of origin that affirmatively says …'I am a product of the United States.'"). Farmers who buy sulfentrazone must read the product label in order to comply with applicable regulations. Kasper ¶ 54. Thus, they necessarily learn the country of origin of the product in the process of reading the label. *Id.* And they naturally make purchasing decisions based upon what they read.

The behavior associated with the tendency to prefer domestic products is called consumer ethnocentrism. Declaration of Naveen Donthu, Ph.D. ¶ 18. The Spartan and Blanket products at issue in this litigation are sold -- and will be sold -- predominately to farmers in the Midwestern United States. Kasper ¶ 52. The culture and demographics of the Midwestern American farmer predict a high likelihood of consumer ethnocentrism. Donthu ¶¶ 18-22, 28-31. When presented with a choice between a product accurately labeled with China as the country of origin and a

product that does not indicate the country of origin (or indicates simply that it is distributed by a U. S. company), American farmers are highly likely to buy the latter product. Donthu ¶ 32.

Such confusion is all that is needed for this Court to find a violation of §43(a) of the Lanham Act. *See Novartis Consumer Health, Inc. v. Johnson & Johnson Merck Consumer Pharm. Co.*, 290 F.3d 578, 586-87 (3d Cir. 2002) ("A 'literally false' message may be either explicit or 'conveyed by necessary implication....'") (quoting *Clorox Co. v. Proctor & Gamble Commercial Co.*, 228 F.3d 24, 35 (1st Cir. 2000)); *Cottrell Ltd. v. Biotrol Int'l, Inc.*, 191 F.3d 1248, 1255-56 (10th Cir. 1999) (false advertising claim was properly alleged when the "label claim...deceives consumers into believing, erroneously, that the EPA has approved [competitor]'s one-week efficacy claim"); *Am. Home Prods. Corp. v. Johnson & Johnson*, 577 F.2d 160, 165 (2d. Cir. 1978) (§43(a) encompasses more than literal falsehoods).

2. FMC Will Be Irreparably Harmed Absent A Preliminary Injunction

In addition to the irreparable harm described, *supra,* 11-13, FMC will suffer the following harm attributable specifically to Defendants' failure to lawfully label their products.

First, as established by the Declarations of John Kasper and Naveen Donthu, Ph.D., it is highly likely that FMC will lose sales because Midwesterners, generally, and American farmers, specifically, will prefer products they perceive to be of domestic origin to products originating overseas. Kasper ¶ 52-54, 57; Donthu ¶ 32. *See Novartis Consumer Health,* 290 F. 3d at 596 (loss of market share constitutes irreparable harm).

Second, FMC will not be able to identify the specific consumers who purchased the Blanket product because FMC does not sell directly to the end-user or consumer. Thus FMC will be unable to reliably quantify all of the millions of dollars of sales lost at the retail counter and the effect that has upon FMC's sales into its channels of distribution. Kasper ¶ 58. *See Salinger v. Colting,* 607 F.3d 68, 81 (2d Cir. 2010) (loss that is difficult to replace or difficult to measure

can be irreparable); *Loretangeli v. Critelli,* 853 F.2d 186, 196 n. 17 (3d Cir. 1988) ("irreparable injury is suffered where monetary damages are difficult to ascertain or are inadequate."); *Syler v. Woodruff*, 610 F. Supp. 2d 256, 263 (S.D.N.Y. 2009) ("it would be extraordinarily difficult for [plaintiff] to delineate with any certainty her lost profits resulting from a lack of traditional book sales or from missed opportunities or sales on the lecture circuit.").

Third, FMC will not be able to identify each retail sale of Blanket to determine those sales lost due to product labeling and those due to unrelated reasons. Kasper ¶ 58. *Coca–Cola Co. v. Tropicana Prods., Inc.*, 690 F.2d 312, 316 (2d Cir.1982) ("Too many market variables enter into the advertising-sales equation. [A] plaintiff who can prove actual lost sales may obtain an injunction even if most of his sales decline is attributable to factors other than a competitor's false advertising."); *Schick Mfg., Inc. v. Gillette Co.*, 372 F. Supp. 2d 273, 282 (D. Conn. 2005) (difficulty in determining that all of the sales decline is due to false advertising makes harm irreparable). "It is difficult to imagine an unfair competition case where damages are adequate to remedy the problem of defendant's continued acts." 5 J. Thomas McCarthy, McCarthy on Trademarks & Unfair Competition § 30.2 (4th ed. 1996).

Fourth, lost sales at the retail counter and the ripple effect back through the chain of distribution will jeopardize the relationships that FMC has built over the course of many years with its distributors and with retailers. Kasper ¶ 59.

Fifth, FMC's investment [redacted] and the expected return on that investment, will be at peril. At minimum, FMC will be unable to quantify the extent to which it was unable to realize a full return on its substantial investment. *Id.* ¶ 57.

3. The Balance of Equities Clearly Favors Entry of a Preliminary Injunction.

The balance of equities favors the requested relief. The harm to FMC is detailed above.

All of these harms will be innocently suffered by FMC because it chooses to comply with the law while Defendants choose to violate it. In contrast, harm to Defendants, if any, will be *de minimis* and will have been self-inflicted. Defendants can sell sulfentrazone produced by a non-infringing process and with a label that accurately identifies its source.

4. The Public Interest Favors Accurate Labeling of Country of Origin In Accordance With the Mandate of the Tariff Act

The relevant public interest is embodied in the plain language of the Tariff Act. Congress presumed that consumers would make buying decisions based, in part, on whether products were of domestic or foreign origin. *See, e.g., Ury*, 106 F.2d at 29 ("Congress was aware that many consumers prefer merchandise produced in this country."); *Friedlaender*, 27 C.C.P.A. at 302 (same).

Likewise, the public policy supporting the Lanham Act establishes the importance that Congress places on accurately designating the country of origin. *Novartis Consumer Health*, 290 F.3d at 597 ("there is a strong public interest in the prevention of misleading advertisements…."); *S&R Corp. v. Jiffy Lube Int'l,, Inc.*, 968 F.2d 371, 379 (3d Cir. 1992) ("In a trademark case, the public interest is 'most often a synonym for the right of the public not to be deceived or confused.'") (quoting *Opticians Ass'n of Am. v. Indep. Opticians of Am.*, 920 F.2d 187, 197 (3d Cir. 1990)). There are no contrary public interests at stake in this litigation.

IV. CONCLUSION

For all of the foregoing reasons, FMC Corporation respectfully requests that its motion for preliminary injunction be granted.

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CERTIFICATE OF SERVICE

I, Daniel M. Silver, hereby certify that on March 6, 2014, I caused a true and correct copy of the foregoing document to be served via email on the following counsel of record:

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